

**REMARKS**

Continued examination of the subject application is respectfully requested.

Claims 1-15 and 32-33 are pending in the present application. Claims 1, 3-15, and 32-33 are being amended. Claim 2 is being cancelled. Claim 34 is being added.

In the final Office Action, claims 1, 2, 4, 5, and 14 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 6,251,126 to Ottenhoff et al. (“Ottenhoff”) and U.S. Patent No. 6,904,320 to Park et al. (“Park”). The remaining claims stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ottenhoff and Park in view of U.S. Patent No. 5,207,230 to Bowers (“Bowers”) and/or U.S. Patent No. 5,158,180 to Kallok (“Kallok”). The previous non-final Office Action rejected claims under 35 U.S.C. § 102 and rejected other claims under 35 U.S.C. § 103(a) as unpatentable over combinations of Park, Bowers, and Kallok, but not including Ottenhoff. The Examiner did not rely on Ottenhoff for any non-final rejection. Amendment after final to overcome the Ottenhoff reference was filed but was not entered because the Examiner said that the Amendment raised new issues.

Independent claims 1 and 7 are being amended to distinctly claim elements not disclosed in prior art cited by the Examiner. In particular, claims 1 and 7 now include (1) determining the patient’s sleep state based upon time of day and postural state, (2) delivering treatment so as to prevent airway collapse if the patient is asleep, (3) determining the presence of an obstruction based upon changes to transthoracic impedance, and (4) increasing said treatment during the

presence of the obstruction. Independent claim 15 is being amended to include a detector to detect transthoracic impedance changes and a controller to elicit vibration to prevent airway collapse if the patient is asleep, to determine the presence of an obstruction based upon changes to transthoracic impedance, and to increase vibration during the presence of an obstruction.

Ottenhoff does not disclose any of these additions to the claims. Ottenhoff determines the patient's sleep state based upon a postural sensor (and not time of day) and then waits a predetermined period of time before sensing respiratory effort through an impedance change (a prerequisite in Ottenhoff to commencing stimulation). Ottenhoff does not deliver stimulation prophylactically but only after measuring an impedance change across the patient's diaphragm, and the stimulation provided does not increase further. In Ottenhoff FIG. 4, stimulation is either on or off but does not increase or decrease once on. In an Advisory Action with mailing date of September 26, 2008, the Examiner stated that Ottenhoff discloses stimulating for any amount of time and discontinuing stimulation when a desired change in impedance is sensed. Although the Examiner is correct in characterizing this aspect of Ottenhoff, the present invention is distinct because it does not discontinue stimulation when a desired change in impedance is sensed.

Park also does not disclose or suggest some of the additions presently being made to the independent claims. Park is directed to sleep apnea therapy using a cardiac stimulator and a physiological sensor. Park determines the patient's sleep state, but not based upon the time of day. Park also does not disclose sensing changes to transthoracic impedance and therefore does not

disclose determining the presence of an obstruction based upon changes to transthoracic impedance or increasing treatment based on changes to transthoracic impedance. In Park, the detection of sleep apnea is limited to sensing cardiac electrical phenomena (col. 4, ln. 56-57) or a physiological sensor to sense physical motion or metabolic demand (col. 5, ln. 55-60), which are distinct from sensing an obstruction by sensing transthoracic impedance changes.

Kallok is directed to a method and apparatus for treating sleep apnea using chronic non-tetanic electrical stimulation. However, Kallok does not disclose determining the patient's sleep state, determining the presence of an obstruction, nor sensing transthoracic impedance.

Bowers is directed to a sensor with a transducer film which attaches to a body portion to record mechanical forces. In contrast, the present invention is used to provide stimulation, not to record mechanical forces. Bowers does not disclose or suggest the use of the sensor or any other device to treat sleep disorders nor does Bowers even suggest providing any stimulation to a patient. Further, Bowers does not suggest sensing changes in transthoracic impedance, nor determining the patient's sleep state.

The Examiner rejected claims 1, 2, 4, 5, and 14 under 35 U.S.C. § 103(a) as being anticipated by Park in view of Ottenhoff (final Office Action paragraphs 5-6). The Examiner rejected claim 1 because Park discloses a method of treating sleep disordered breathing comprising the step of applying electrical stimulation of nerves to increase muscle tone of upper airway muscles and

Ottenhoff discloses determining the likelihood of a patient being asleep and applying electrical stimulation based on that likelihood. As stated above, claim 1 is being amended to include the steps of delivering treatment to prevent airway collapse if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. Neither Ottenhoff nor Park discloses nor suggests delivering therapy so as to prevent airway collapse, determining the patient's sleep state based on both time of day and postural state, or determining the presence of an obstruction based upon change in transthoracic impedance and thereby increasing delivery of therapy. It is believed that claim 1 is now in condition for allowance. In addition, because claims 4, 5, and 14 depend from claim 1, it is believed that those claims are also in condition for allowance.

The Examiner rejected claims 3, 6, 13, and 32 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff and in view of Kallok (final Office Action paragraphs 7-10). With regard to claim 3, the Examiner stated that Kallok discloses that the site of electrical stimulation is within or adjacent to the genioglossus muscle (col. 3, ln. 38-41). With regard to claim 6, the Examiner stated that Kallok discloses a train length of around 50 pulses. With regard to claims 13 and 32, the Examiner stated that Kallok discloses repeated stimulation in accordance with the detected state of the airway. However, Kallok discloses sensing the tension of the stimulated muscle tissue (col. 2, ln. 24-29) and does not disclose determining the presence of an obstruction. In addition, Kallok, like Park and Ottenhoff, does not disclose or suggest delivering therapy to prevent

airway collapse, to increase therapy upon determining the presence of an obstruction, or to sense transthoracic impedance changes. As presently amended, claims 3, 6, and 13 include the steps in claim 1 of delivering treatment to prevent airway collapse if the patient is asleep, to determine the presence of an obstruction in said patient's airway by sensing transthoracic impedance changes, and if an obstruction is present to increase treatment until said obstruction is no longer present. None of these limitations is disclosed or suggested in Park, Ottenhoff, or Kallok. Therefore, it is believed that claims 3, 6, and 13 are presently in condition for allowance.

In addition, claim 32 is dependent from claim 7. Claim 7 is presently being amended to include the steps of delivering treatment to prevent airway collapse if the patient is asleep, determining the presence of an obstruction in said patient's airway by sensing transthoracic impedance changes, and if an obstruction is present increasing treatment until said obstruction is no longer present. Again, these limitations are not disclosed or suggested by Park, Ottenhoff, or Kallok. It is believed claim 32 is also in condition for allowance.

The Examiner rejected claims 7, 10-12, and 33 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff and in view of Bowers (Office Action paragraphs 11-15). Particularly regarding claim 7, the Examiner stated that Bowers discloses a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles. However, the passage cited by the Examiner (col. 3, ln. 20-23) does not disclose or suggest anything relative to treating sleep

disordered breathing and treating sleep disordered breathing is not disclosed or suggested anywhere else in Bowers. As presently amended, claim 7 is directed to treating sleep disordered breathing and includes the steps of delivering treatment to prevent airway collapse if the patient is asleep, determining if the presence of an obstruction in said patient's airway by sensing, and if an obstruction is present increasing treatment. These steps are not disclosed or suggested in any of Ottenhoff, Park, and Bowers. Therefore, it is believed that claim 7 is in condition for allowance.

In addition, regarding claims 10-12, the Examiner cited Bowers (col. 10, ln. 25-30) for periodic mechanical stimulation, periodicity in the order of several seconds, and low mechanical frequency. However, claims 10-12 are dependent from claim 7 which, as described above, is distinct from Bowers, Ottenhoff, and Park. Therefore, it is believed that claim 7 is in condition for allowance.

In addition, regarding claim 33, the Examiner noted that Park discloses stimulation carried out in accordance with a model of Cheyne-Stokes Respiration (col. 7, ln. 41-44). However, the limitations of claim 7 as presently amended are not disclosed in Park or in Bowers or Ottenhoff. Therefore, it is believed that claim 33 also is presently in condition for allowance.

The Examiner rejected claims 8, 9, 15, and 31 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff, in view of Bowers and in view of Kallok. (Final Office Action paragraphs 16-18). Regarding claims 8 and 9, although the Examiner noted that Bowers discloses mechanical stimulation by a piezo electric mechanical element and Kallok discloses an element implanted

at or near the genioglossus muscle, claims 8 and 9 depend from claim 7. As presently amended, claim 7 includes the steps of delivering treatment to prevent airway collapse if the patient is asleep, to determine the presence of an obstruction in said patient's airway by sensing transthoracic impedance changes, and if an obstruction is present to increase treatment until said obstruction is no longer present. These steps are not disclosed or suggested by Park, Ottenhoff, Bowers, or Kallok. It is believed that as a result claims 8 and 9 are presently in condition for allowance.

In addition, regarding claim 15, the Examiner stated that Park in view of Ottenhoff, in view of Bowers, and in view of Kallok discloses an apparatus for treating respiratory disorders comprising a piezo-electric mechanical element (Bowers: col. 3, ln. 20-23), a controller adapted to elicit vibration of the element via an electrical signal (Park: col. 22, ln. 37-38), a real time clock for determining time of day (no cite provided), a position sensor for sensing postural state (Ottenhoff: col. 5, ln. 32-36), and an apparatus adapted for implant at or near the base of the genioglossus muscle (Kallok: col. 3, ln. 38-41). Claim 15 is presently being amended to include a detector to detect transthoracic impedance changes and a controller to deliver vibration to prevent airway collapse if the patient is asleep, to determine the presence of an obstruction based upon changes to transthoracic impedance, and to increase vibration during the presence of an obstruction, none of which is disclosed or suggested by Park, Ottenhoff, Bowers, or Kallok. Therefore, it is believed that claim 15 is in condition for allowance.

Finally, claim 31 had previously been cancelled.

The allowance of claims 1, 3-15, and 32-34 and the early passage to issue of the application are respectfully requested.

Respectfully submitted,  
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